

K101646

SEP 08 2010

APPENDIX M

**510(k) SUMMARY
SUMMARY OF THE SAFETY AND EFFECTIVENESS FOR
NON-STERILE, POWDER FREE BLACK NITRILE EXAMINATION GLOVES
WITH CHERRY FLAVOR**

Submitted For : SGMP Company Limited, 181 Moo 6, Tambol Kampaengpetch, Rattaphum, Songkhla 90180, Thailand.

Submitted By: Tucker & Associates
Official Correspondent for SGMP Co Ltd
Janna P. Tucker, President – CEO
198 Avenue de la D'emerald, Sparks, NV 89434-9550
Phone No : 775-342-2612 Fax No : 775-342-2613
E-mail: Tuckerjan@aol.com

Equivalent Predicate Device: POWDER FREE BLACK NITRILE EXAM GLOVES which was granted a 510(k) # K072400

Device Information:

Trade Name – Non-Sterile, Powder Free Black Nitrile Examination Gloves with Cherry Flavor
Common Name - Exam gloves
Classification Name - Patient examination glove (per 21 CFR 880.6250)
Classification Information - Class I Nitrile examination glove 80LZA, powder free and meeting all the requirements of ASTM D6319-00a (2005) Standard Specification for Nitrile Examination Gloves for Medical Application.

Device Description:

Class I Nitrile examination gloves 80LZA, powder free and meeting all the requirements of ASTM D6319-00a (2005) Standard Specification for Nitrile Examination Gloves for Medical Application.

Intended Use of Device:

A medical glove to be worn on the hand of the health care and similar personnel to prevent contamination between health care personnel and patient.

Conclusion:

The data presented indicate the Non-Sterile, Powder-Free Black Nitrile Examination Gloves with Cherry Flavor meets the following Standards:

1. ASTM D6319-00a00a(2005), Standard Specification for Nitrile Gloves.
2. ISO 2859-1, Standard for Water Leak Test and/or ASTM D5151-06, Test Method for Detection of Holes in Medical Gloves.
3. ASTM D6124-06, Standard Test Method for Residual Powder on Medical Gloves.
4. Biocompatibility Testing on White Rabbits and Guinea Pigs.
5. Labeling meets FDA Specifications.
6. Except for flavor, this glove is equivalent to K072400.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

SGMP Company, Limited
C/O Ms. Janna P. Tucker
Tucker & Associates
198 Avenue De La D'Emerald
Sparks, Nevada 89434

SEP 08 2010

Re: K101646

Trade/Device Name: Non-Sterile, Powder Free Black Nitrile Examination Gloves with Cherry Flavor

Regulation Number: 21 CFR 880.6250

Regulation Name: Patient Examination Glove

Regulatory Class: I

Product Code: LZA

Dated: June 10, 2010

Received: June 11, 2010

Dear Ms. Tucker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucml15809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

 for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

K101646

SEP 08 2010

Applicant : SGMP Company Limited

510K NUMBER :

Device Name : Non-Sterile, Powder Free Black Nitrile Examination Gloves with Cherry Flavor

Indication For Use :

The Non-sterile Powder Free Black Nitrile Examination Gloves with Cherry Flavor, is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Prescription Use
(Part 21 CFR 801.Subpart D)

AND / OR

Over-The-Counter.....
21 CFR 801 Subpart C

.....
Concurrence of CDRH , Office of Device Evaluation (ODE)

Elizabeth F. Clavie-Wallace
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K101646